arms were compared: cohort A patients (high-risk) treated by either TAVR (n=149) or surgical aortic valve replacement (SAVR, n=138); and cohort B patients (considered inoperable) treated by either TAVR (n=72) or medical therapy only (MedTx, n=95).
Results: In the total group of patients included in the PARTNER trial who underwent TAVR, those having no COPD (n=1096) and non-O2-dep COPD (n=627) had better 1-year survival than did O2-dep COPD patients (n=215). (Table) O2-dep COPD patients who underwent TAVR and survived for 1 year had relatively low rates of high functional class (NYHA class I/II): 79.2% of cohort A patients; 52.4% of cohort B. There were no differences in baseline characteristics between the TAVR and control groups in the different subgroups evaluated. In cohort A patients, 1-year outcomes did not differ significantly between TAVR and SAVR. In cohort B patients, TAVR, compared to MedTx, improved 1-year survival free of hospitalization but not 1-year survival. (Table)
Conclusions: Patients with severe COPD and severe AS are at higher risk for worse clinical outcome and lower survival. In COPD patients, TAVR had better outcome than did medical therapy but showed no benefit over SAVR.

	All TAVR patients				COPD patients (TAVR vs. control)					
	No COPD n=1096	non-O2dep COPD n=627	O2 dep COPD n=215	p Value	TAVR n=149	SAVR n=138	p Value	TAVR n=72	MedTx n=95	p Value
1-year survival (%)	85.0	84.1	76.9	0.02	75.0	73.1	0.60	62.5	47.8	0.12
1-year survival free from hospitalization (%)	79.2	78.3	69.7	0.01	65.5	63.0	0.57	51.4	30.1	0.03

TCT-95

Outcomes of Transcatheter vs. Surgical Aortic Valve Replacement in Women: Insights from the Randomized PARTNER Trial

Mathew Williams[1], Susheel Kodali[2], Karin Humphries[3], Vuyisile Nkomo[4], Lars Svensson[5], Neil Weissman[6], David Cohen[7], Vinod Thourani[8], Michael Mack[9], E Murat Tuzcu[10], Irene Hueter[11], Maria Alu[12], Ajay Kirtane[13], Martin Leon[14]
[1]Columbia University, New York, USA, [2]Columbia, New York, USA, [3]Providence Health System, Vancouver, British Columbia, [4]Mayo Clinic, Rochester, MN, [5]Cleveland Clinic, Cleveland, USA, [6]MedStar Washington Hosp Center, Washington, USA, [7]Saint Luke's Mid America Heart Institute, Kansas City, USA, [8]Emory University, Atlanta, GA, [9]Baylor Healthcare System, Plano, USA, [10]Cleveland Clinic, Cleveland, OH, [11]Cardiovascular Research Foundation, New York, NY, [12]Columbia University Medical Center, New York, NY, [13]Columbia University / Cardiovascular Research Foundation, New York, NY, [14]Cardiovascular Research Foundation, New York, USA

Background: The PARTNER Trial demonstrated that transcatheter aortic valve replacement (TAVR) in high surgical risk patients with aortic stenosis was non-inferior to surgical AVR. Whether there are gender-specific differences in the application of TAVR to this high-risk population are unknown.
Methods: Patients enrolled in the high-surgical risk cohort of the PARTNER Trial (Cohort A) were included in this analysis (n=697). Gender-specific differences in baseline characteristics and outcomes at 2 years of follow-up were compared by randomized treatment assignment.
Results: Despite greater age (84.9 vs. 83.4, p<0.01), and slightly higher median STS scores (11.1 vs. 11.0, p=0.03), women (n=298) had a lower prevalence of important comorbidities, including diabetes (35.6% vs. 45.6%, p<0.01), smoking history (33.2% vs. 60.7%, p<0.001), coronary artery disease (64.4% vs. 83.7%, p<0.001), prior CABG (19.8% vs. 60.4%, p<0.001), peripheral vascular disease (36.4% vs. 46.9%, p<0.01), and chronic kidney disease (11.7% vs. 23.9%, p<0.001). There were no differences in outcomes at 30 days between TAVR and surgery in women; among TAVR patients, there were similar rates of both mortality (4.1% vs. 3.0%, p=0.58) and stroke (5.5% vs. 4.0%, p=0.52) in women compared to men. Compared to surgery, women undergoing TAVR had better one (18.5% vs. 29.5%, p=0.02) and 2-year (28.6% vs. 38.6%, p=0.05) survival, whereas, among men, there was no difference at either one (28.5% vs. 25.2%, p=0.67) or 2 years (37.5% vs. 32.1%, p=0.43). Compared to surgery, women undergoing TAVR had higher stroke rates at 1 year (7.1% vs. 0.7%, p<0.01); this difference was not seen in men (5.3% vs. 5.0%, p=0.90). There was a significant treatment-gender interaction for mortality and stroke at 1 but not 2 years, with no significant interactions for other outcomes.
Conclusions: Gender-specific differences in outcomes (beyond 30 days) were observed among randomized patients in PARTNER suggesting TAVR may be the preferred therapy among women. Further investigation is required to determine whether this benefit can be attributed specifically to gender, or whether other factors may be involved.

TCT-96

Influence Of Gender On Clinical Outcomes Following Transcatheter Aortic Valve Implantation: Results From The UK TAVI Registry On Behalf Of The UK TAVI Steering Group And The National Institute For Cardiovascular Outcomes Research

Rasha Al-Lamee[1], Christopher Broyd[2], Jessica Parker[3], Justin Davies[2], Jamil Mayet[2], Nilesh Sutaria[3], Ben Ariff[3], Beth Unsworth[2], John Cousins[3], Colin Bicknell[3], Jon Anderson[3], Iqbal Malik[3], Andrew Chukwuemeka[3], Neil Moat[4], Peter Ludman[5], Darrel Francis[2], Ghada Mikhail[3]
[1]Imperial College NHS Trust, London, [2]Imperial College, London, [3]Imperial College NHS Trust, London, [4]Royal Brompton Hospital, London, [5]University Hospital, Birmingham

Background: Female sex is associated with adverse outcomes following conventional aortic valve replacement. We investigate gender differences following transcatheter aortic valve implantation (TAVI) in the UK's National Institute for Cardiovascular Outcomes Research (NICOR) TAVI Registry.
Methods: Retrospective analysis of 1627 patients enrolled in a UK multicentre registry from January 2007 to December 2010. TAVI was conducted via transfemoral, transapical, subclavian/transaxillary and transaortic access routes with implantation of Medtronic CoreValve ReValving System®, Edwards SAPIENTM and SAPIEN XTTM devices.
Results: TAVI was performed in 756 (46.5%) females and 871 (53.5%) males aged 82.6±6.8 years and 80.8±7.6 years respectively. Females had a higher peak aortic gradient (84.4±28.6mmHg v 76.6±24.5mmHg; p<0.001) and smaller aortic annulus diameter (21.1±2.8mm v 23.0±3.1mm; p<0.001). Men had greater prevalence of type II diabetes (23.9% v 19.2%; p=0.021), poor left ventricular systolic function (11.9% v 5.5%; p<0.001), three vessel coronary artery disease (19.4% v 9.2%; p<0.001), left main stem disease (8.0% v 3.2%; p<0.001), previous myocardial infarction (29.5% v 13.0%; p<0.005), peripheral vascular disease (32.4% v 23.3%; p<0.001) and higher logistic EuroSCORE (21.8±14.2% v 21.0±13.4%; p=0.046). Kaplan-Meier mortality at 30 days was 6.3% (95% CI 4.3% to 7.9%) in women and 7.4% (5.6% to 9.2%) in men. At 6 months, 14.1% (11.5% to 16.7%) and 16.6% (14.0% to 16.6%) respectively. At 1 year 21.9% (18.7% to 25.1%) and 22.4% (19.4% to 25.4%) respectively. There was no difference in mortality: p=0.331 by log-rank test; hazard ratio for women 0.911 (0.754 to 1.100). There was no difference in device success rate (96.6% in women v 96.4% in men; p=0.889) or cerebrovascular event rate at 30 days (3.8% v 3.7%; p=0.962). However, women had significantly more major vascular complications than men (7.5% v 4.2%; p=0.004).
Conclusions: Despite a higher risk profile in males there was no difference in mortality, procedural success or cerebrovascular event rate between genders. However, women had almost twice the rate of major vascular complications compared with men.

Transcatheter Aortic Valve Replacement II

D240-241

Tuesday, October 23, 2012, 10:30 AM–12:30 PM

Abstract nos: 97-104

TCT-97

Three-dimensional Echocardiographic Measurements of the Aortic Annulus Predict Paravavular Regurgitation following Transcatheter Aortic Valve Replacement

Rebecca Hahn[1], Jean-Michel Paradis[1], Benoit Daneault[1], Susheel Kodali[1], Elana Koss[1], Isaac George[1], Martin Leon[2], Mathew Williams[1]
[1]Columbia University, New York, NY, [2]Cardiovascular Research Foundation, New York, NY

Background: Background Paravalvular regurgitation (PVR) after transcatheter aortic valve replacement (TAVR) is associated with adverse outcomes. Studies evaluating the utility of three-dimensional echo (3DE) are limited. We performed a retrospective analysis using 3DE-derived annular measurements and evaluated their ability to predict PVR.
Methods: 58 TAVR patients were evaluated: 35 patients who receive a post-dilatation for paravalvular regurgitation (PD) and 23 who did not (NoPD). Intra-procedural trans-esophageal echocardiography was performed with both two-dimensional (2DE) and 3DE imaging. PVR areas seen on a short axis view were measured immediately following deployment. Pre-TAVR annular dimensions included the sagittal 2DE annular diameter and 3DE measurements of: minimal diameter, maximal diameter, mean diameter, average diameter and area. A cover index was calculated using these diameters. An area cover index was also calculated using nominal areas of the THV and the 3DE.
Results: PD patients were more often male (p=0.01) and had larger BSA (1.83± 0.24 vs. 1.67± 0.23 m2, p=0.013) and a higher annular eccentricity index (13.6± 5.1 vs. 8.01± 5.3, p=0.001). Following TAVR, PD patients had larger PVR areas immediately following deployment (40.3± 17.1 vs. 15.4± 14.2mm2, p<0.0001). These patients had a lower cover index irrespective of the annular diameter used (Table). All measurements

ORALS

were linearly related to PVR (Table)however the highest correlation with the severity of PVR was seen with the maximum diameter (r2=0.48, p<0.001), mean diameter(r2=0.47, p<0.0001), average diameter (r2=0.48, p<0.0001) or the annular area (r2=0.48, p<0.0001).
Conclusions: This study demonstrates that 3DE measurements of the aortic annulus are feasible and are better predictors of PVR after TAVR than 2D sagittal diameter and should be incorporated into the algorithm for balloon-expandable transcatheter valve sizing.

Comparison of 2DE and 3DE Measurements				
Cover Index	NoPD (n=23)	PD (n=35)	p-value	r2 for linear measure
2DE Sagittal	10.14 ± 4.02	6.89 ± 3.24	0.002	0.26 (p = 0.001)
3DE Minimum	16.19 ± 6.39	10.88 ± 4.91	0.001	0.36 (p<0.0001)
3DE Maximum	8.67 ± 7.87	-2.74 ± 6.50	< 0.001	0.48 (p<0.0001)
3DE Mean	12.44 ± 6.65	4.07 ± 4.71	< 0.001	0.47 (p<0.0001)
3DE Average	11.50 ± 6.11	2.68 ± 4.93	< 0.001	0.48 (p<0.0001)
3DE Area	23.09 ± 10.32	7.91 ± 9.14	< 0.001	0.48 (p<0.0001)

TCT-98

The Impact of Effective Aortic Annulus Sizing by 3D Computed Tomography on Paravalvular Leak Development after Transcatheter Aortic Valve Implantation

Fabian Plank[1], Thomas Bartel[2], Silvana Müller[3], Gudrun Feuchtner[1], Anneliese Heinz[1], Guy Friedrich[2], Nikos Bonaros[2]
[1]Innsbruck Medical University, Innsbruck, Austria, [2]Medical University Innsbruck, Innsbruck, Austria, [3]Innsbruck Medical University, 6020, Austria

Background: Despite excellent outcome after transcatheter aortic valve implantation (TAVI), paravalvular leaks may occur. Objective of this study was to evaluate annulus sizing by 3-D computed tomography (CT) for prediction of paravalvular leaks after TAVI, and to compare CT with transesophageal (TEE) and intracardiac echocardiography (ICE).
Methods: In 88 patients (mean, 83yrs) with severe aortic stenosis who underwent TAVI, transesophageal (TEE), intracardiac echocardiography (ICE) and ECG-gated CT-Angiography were performed before device implantation. Two-(ML/AP), three-annulus diameter (RC/LC/NC) and the annulus area were measured on CTA. "Undersizing" was defined as CT annulus–prosthetic heart valve (PHV) size; "annulus eccentricity" as AP/ML-annulus diameter ratio. Post-procedural echocardiography was performed immediately after, and at 1, 3,6, 12 and 24 month after the procedure and severity of paravalvular leaks graded.
Results: Of 88 implanted prosthetic heart valves (PHV) 22 (25%) had none, 46 (52.3%) mild, 11 (12.5%) mild-to-moderate, 9 (10.2%) moderate or moderate-to-severe, and 0% severe leaks. Both TEE and ICE measured smaller mean annulus diameters than CT (mean:-2,84mm and -2.19mm, resp., p<0.01). Overall, 53% of PHV were undersized, in only 3/22 (14%) patients with no leaks and in 35/66 (53%) with leaks. Undersizing was higher in those with leaks as compared to those without (1mm vs 0.2mm, p<0.01). No difference between mild and moderate-to-severe (1mm vs. 1.2mm, p=0.64) leaks were found for the mean of 3-annulus diameters. The annulus area undersizing was higher in patients with leaks than in those without (0.44cm2 vs 0.14cm2, p<0.05), however the annulus eccentricity index was not different (0.82 vs. 0.82, p=0.06). If applying the 3- instead of 2-diameter annular CT measurements, 4 (5%) patients without leaks and 2 (2%) with leaks were reclassified as not-undersized and undersized, respectively.
Conclusions: PHV undersizing relative to CT annulus dimensions is associated with paravalvular leaks after TAVI, but not annulus eccentricity. Three-diameter annulus sizing by CT may be more accurate than the two-diameter method.

TCT-99

The Vancouver Computed Tomography Sizing Guidelines for Transcatheter Aortic Valve Replacement with Balloon Expandable Valves

Alex Willson[1], Webb John[2], Melanie Freeman[1], David Wood[1], Ronen Gurvitch[1], Chris Thompson[1], Robert Moss[1], Stefan Toggweiler[1], Ronald Binder[1], Brad Munt[1], Anson Cheung[1], Cameron Hague[1], Jian Ye[1], Jonathon Leipsic[1]
[1]St Pauls Hospital, Vancouver, British Columbia, [2]St Pauls Hospital, Vancouver, british Columbia

Background: To develop computed tomography (CT) sizing guidelines for transcatheter aortic valve replacement (TAVR). CT annular measurements are predictive of paravalvular regurgitation post TAVR; a predictor of mortality and morbidity.
Methods: The Vancouver CT sizing guidelines aim to ensure routine transcatheter heart valve (THV) over sizing of the aortic annulus (range:1-20%, target 10-15%). Percentage of over sizing is defined as (THV external area/annular area-1) x 100. 120 consecutive patients underwent CT prior to TAVR with balloon expandable valves using transesophageal echocardiography (TEE) sizing recommendations. The Vancouver CT sizing guidelines recommended prosthesis size was compared to the actual size implanted.
Results: As compared to TEE sizing recommendations, the Vancouver CT sizing guidelines recommended a larger valve in 33.3% (40/120), no change in valve size in 55.8% (67/120) and a smaller valve in 10.8%(13/120). In patients where CT guidelines would have recommended a larger valve, the incidence of at least moderate paravalvular regurgitation was 25% (10/40), compared to only 4.5% (3/67, p<0.01) when both TEE and CT guidelines were in agreement. Traditional TEE sizing methods resulted in 33.3%(40/120) of valves being under sized (THV area<CT annular area) with a mean annular over sizing of 9.4±17.4% (range: -21.5 to 65.9%) without annular rupture. In contrast, the Vancouver CT sizing guidelines results in mean annular over sizing of 13.9±8.0% (range: 1.3-29.8%).
Conclusions: The Vancouver CT sizing guidelines enable standardized moderate over expansion of the annulus that is likely to result in significantly lower rates of paravalvular regurgitation.

TCT-100

Transcatheter Aortic Valve Replacement for Degenerative Bioprosthetic Surgical Valves: Results from the Global Valve-in-Valve Registry

Danny Dvir[1], John Webb[2], Miralem Pasic[3], Sabine Bleiziffer[4], Ron Waksman[5], Ulrich Schäfer[6], Antonio Colombo[7], Josep Rodes-Cabau[8], Hendrik Treede[9], David Hildick-Smith[10], Fleur Descoutures[11], Thomas Walther[12], Christian Hengstenberg[13], Henrik Nissen[14], Raffi Bekeredjian[15], Enrico Ferrari[16], Stephan Windecker[17], Stephen Brecker[18], Jean-Claude Laborde[19], Ran Kornowski[20]
[1]Washington Hospital center, washington, DC, [2]St Pauls Hospital, Vancouver, British Columbia, [3]Deutsches Herzzentrum Berlin, Berlin, Germany, [4]German Heart Center Munich, Munich, Germany, [5]Georgtown University, Washington, DC, [6]Asklepios Klinik St. Georg - University of Hamburg, Hamburg, Hamburg, [7]EMO GVM Centro Cuore Columbus srl, Milan, Italy, [8]Quebec Heart and Lung Institute, Quebec, Canada, [9]Hamburg University, Hamburg, Germany, [10]Royal Sussex County Hospital, Brighton, United Kingdom, [11]Hospital Bichat, Paris, France, Paris, France, [12]Kerckhoff Heartcenter, Bad Nauheim, Germany, Bad Nauheim, Germany, [13]University of Regensburg Medical Center, Regensburg, Bavaria, [14]Odense University Hospital, Odense C, Denmark, [15]Heidelberg University Hospital, Heidelberg, Germany, [16]University Hospital of Lausanne, Lausanne, Switzerland, [17]Bern University Hospital, Bern, Switzerland, [18]St. George's Hospital, London, United Kingdom, [19]St.George hospital, London, Plumtree Nottingham, United Kingdom, [20]Professor of Cardiovascular Medicine, Tel Aviv University, Petach Tikva, Israel

Background: Transcatheter aortic valve-in-valve (VIV) implantation is an emerging therapeutic alternative for patients with failed surgical bioprosthesis and may obviate the need for a redo surgery. We aimed to evaluate the clinical results of this technique using a large worldwide registry.
Methods: The registry included 416 patients with degenerated aortic bioprosthetic valves (age 77.7 ± 9.7 years; 55.3% men) from 54 cardiac centers. The mode of failure was stenosis (n=168, 40.4%), regurgitation (n=125, 30%), and combined stenosis and regurgitation (n=123, 29.6%). Implanted devices were Edwards SAPIEN (n=225), CoreValve (n=190) and Melody (n=1).
Results: Adverse procedural outcomes included 11.1% device malposition and 1.9% ostial coronary obstruction. Post-procedure, valve maximum / mean gradients were 28.5 ± 14.3 mmHg / 16.1 ± 9.0, respectively. Independent predictors for high post-procedural gradients (mean ≥20 mmHg) were baseline bioprosthesis stenosis [vs. regurgitation, odds ratio (OR), 6.33, p < 0.001)] and the use of the Edwards SAPIEN device (OR 2.1, p= 0.008). At 30-day follow-up, all-cause mortality was 7.8% and 87.5% of patients were at New York Heart Association functional class I/II. One-year survival was 82.6%. The strongest independent predictor for 1-year mortality post VIV was baseline bioprosthesis stenosis (vs. regurgitation, OR 3.7, p=0.003).
Conclusions: The VIV procedure is clinically effective in most patients, with 1-year results comparable with other TAVR cohorts. Baseline bioprosthetic stenosis is the strongest predictor for both elevated post-procedural gradients and 1-year mortality.

TCT-101

12M Results of a 2nd Generation Transapical Aortic Bioprosthesis for the Treatment of Patients with Severe Aortic Stenosis

Joerg Kempfert[1], David Holzhey[2], Hendrik Treede[3], Matthias Thielmann[4], Stephan Sorg[5], H. Schroefel[6], Friedrich Mohr[7], Thomas Walther[8]
[1]Kerckhoff-Klinikum, Bad Nauheim, Germany, [2]University of Leipzig - Heart Center, Leipzig, Germany, [3]Hamburg University, Hamburg, Germany, [4]West German Heart Center, Essen, Germany, [5]Universitätsklinikum Freiburg Chirurgische UNI-Klinik, Freiburg, Germany, [6]Clinic for Cardiac Surgery, Karlsruhe, Germany, [7]University of Leipzig, Leipzig, Germany, [8]Kerckhoff Heartcenter, Bad Nauheim, Germany, Bad Nauheim, Germany

Background: A novel, innovative transapical aortic valve implantation (TA-TAVI) system completed enrollment (n=90) in two pre-market studies. The TA device received